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## ATTACHMENT 11

**SUMMARY OF SAFETY AND EFFECTIVENESS**  
**Hitachi EUB-8000 Ultrasound Electronic Scanner****Device Description**

The Hitachi EUB-8000 Ultrasound Electronic Scanner is a Track 3 diagnostic ultrasound system capable of the following operating modes: B, M, Pulsed Doppler, Color Flow, and Continuous Wave Doppler. Probes available with the EUB-8000 are intended for the following general clinical uses: Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral Vascular, Biopsy, Transrectal, Transvaginal, and Neonatal Cephalic. The EUB-8000 utilizes digital front-end electronics for detection of echo signals.

**Safety**

As a Track 3 ultrasound system, the Hitachi EUB-8000 Ultrasound Electronic Scanner complies with the "Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (1992), published by the National Electrical Manufacturers Association as UD-3. With respect to limits on acoustic outputs, the Hitachi EUB-8000 Ultrasound Electronic Scanner complies with the guideline limits set in the April 14, 1994, Revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the Hitachi EUB-8000 Ultrasound Electronic Scanner will be designed to comply with the IEC 601-1 (1988) Medical Electrical Equipment, Part 1, General Requirements for Safety.